K111939

JUL 11 2012

FLEXICATH

510(K) Summary
For Flexicath M/29™ Pressure Injectable Peripherally Inserted Catheter Device

Date Prepared: 27 June, 2012

510(k) owner name:

Company name:	Flexicath Ltd.
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Contact person:

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Device Name:

Common or usual name: Peripherally Inserted Catheter
Proprietary/Trade name: M/29™ Pressure Injectable

Classification name: M/29™ Pressure Injectable has been classified as **Class II** device under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days	FOZ	880.5200	General Hospital

Predicate Devices:

1) *Flexicath's FirmGrip™ Peripherally Inserted Catheter Device*, cleared under 510(k) number: **K080793** *and;*
2) *Flexicath's FirmGrip™ Peripherally Inserted Catheter Device* with the *SNM* (Safety Needle Mechanism) *feature, cleared under* 510(k) number: **K092629** *and;*
3) *Arrow's Antimicrobial Pressure Injectable PICC,* cleared under 510(k) number: **K100635**.

Device description:

Flexicath's *M/29™ Pressure Injectable* device is actually the very same device cleared under K080793 (FirmGrip - Peripherally Inserted Catheter) and K092629 (same device with the addition of the Safety Needle Mechanism (SNM).
It is also similar to Arrow's Pressure Injectable PICC and has the very same claim (use with pressure injection of up to 300psi or 5ml/sec flow rate). Other aspects of Arrow's device are **not** relevant to our M/29 catheter (such as: antimicrobial claim; being used as PICC and; time duration exceeding 29 days).

The main addition in Flexicath M/29 Catheter within this submission is to allow high pressure applications at up to 300psi or 5ml/sec flow rate.

No redesign of M/29 catheter or engineering modifications took place in order to comply with this pressure and flow rate definition. The components' list and materials remain the same as in Flexicath's predicate devices indicated above. The mode of operation of Flexicath's M/29 also remain the same but with the addition of meeting the pressure injection claim for up to 300psi or 5ml/sec.

The indication for use was revised in order to reflect the additional claim for pressure injection.

Several minor other modification (not relevant to the pressure injection), are presented in our submission. The changes are:

a) A color change of the friction unit: from natural to pink colorant in order to make it more visible.
b) A 10cm length catheter unit assembly was added in addition to the current length exists.
c) The single unit package was changed from a pouch to a hard (rigid) blister.
d) A luer cap was added separately within the blister package as an accessory to close the catheter's female luer connection when open.

Intended use:

The Pressure Injectable M/29TM is a Peripherally Inserted Catheter Device which is intended for use in patients requiring repeated access to the peripheral venous system for infusion or injection intravenous therapies and/or blood sampling and pressure injection applications such as contrast media injection.
The maximum flow rate for Flexicath Pressure Injectable midline catheter may not exceed 5ml/sec.

Technological characteristics and Substantial Equivalence:

The new device is substantially equivalent with three already cleared devices as identified above under "predicate devices" section.
Both new and predicate devices have the same or very similar indication for use, same basic shape, design and characteristics. The new device was established by Flexicath as being suitable for pressure injections under the defined parameters.
All changes that differs the new device from the predicate devices were fully addressed and evaluated.

New device's verification and validation tests showed that it is as safe and as effective as the predicate devices and substantial equivalent to the predicates.

None clinical performance data:

Tests results are supporting all labeling claims and substantial equivalency.
The new device was tested with accordance to Flexicath's legally marketed device specification and applicable standards. The **pressure injection** performances were tested according to applicable standards and by using Arrow's predicate device information as a 'gold standard'. All tests' acceptance criteria were met.

Conclusions:

The evaluation of Flexicath's M/29^{TM} Pressure Injectable - Peripherally Inserted Catheter Device non-clinical tests, demonstrates that the device is as safe and as effective as the predicate devices and that all performance tests' acceptance criteria were met. Therefore, we believe it is substantially equivalent with the selected predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Flexicath Ltd.
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Regulatory Affairs Advisor
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Re: K111939
Trade/Device Name: M/29™ Pressure Injectable
Regulation Number: 21 CFR 880.5200
Regulation Name: Catheter, Intravascular, Therapeutic, Short-term, Less than 30 days
Regulatory Class: II
Product Code: FOZ
Dated: July 4, 2012
Received: July 6, 2012

Dear Ms. Hazan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

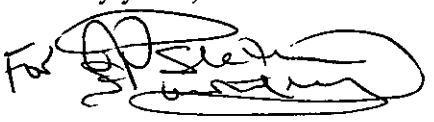
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indication For Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111939

Device Name: M/29™ – Pressure Injectable

Indications for use: The Pressure Injectable M/29TM is a Peripherally Inserted Catheter Device which is intended for use in patients requiring repeated access to the peripheral venous system for infusion or injection intravenous therapies and/or blood sampling and pressure injection applications such as contrast media injection.
The maximum flow rate for Flexicath Pressure Injectable midline catheter may not exceed 5ml/sec.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AN/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

7/10/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111939